Genentech
IN BUSINESS FOR LIFE

DEPARTMENT OF REGULATORY AFFAIRS

1 DNA Way MS#242
South San Francisco, CA 94080-4990
(650) 225-1558
FAX: (650) 467-3198

December 8, 2006

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Subject: **Docket No. 2006N-0464**
Electronic Submission of Regulatory Information, and Creating an Electronic Platform for Enhanced Information Management; Public Hearing

Dear Dockets Management Branch:

Enclosed are comments, provided by Genentech, to docket 2006N-0464.

Thank you for providing us the opportunity to comment on this Draft Guidance. We hope that you will find our comments useful and constructive.

Sincerely,

Robert L. Garnick, Ph.D.
Senior Vice President
Regulatory Affairs, Quality,
and Compliance

Docket-025 ss

The following comments are provided by Genentech, Inc. on Docket no. 2006N-0464, "Electronic Submission of Regulatory Information, and Creating an Electronic Platform for Enhanced Information Management; Public Hearing". We welcome FDA's efforts to solicit comments concerning future electronic initiatives.

A. 4. IMPLEMENTATION

- Should we consider an incremental phase-in implementation strategy for an all-electronic submission environment?

  Yes, we believe this would be necessary so that sponsors, vendors, and reviewers could adjust to the required process changes gradually. This would allow all parties to learn from each phase and apply that knowledge to the next phase, making the following phases more efficient. It would also prevent the parties and systems from becoming overwhelmed and unable to process all systems electronically in an accurate and timely manner.

- Is so, what should the strategy include?

  The first phase should include all electronic submissions using the current file types (e.g., PDF, SAS, XML backbone).

  Next, there should be incremental conversion to XML content for the different document types (e.g., Forms, Protocols, IBs).

- What is the order of priorities for phasing in implementation?

  For XML content:

  1. Forms (1571, 356h, etc.),
  2. Protocols
  3. Investigational Brochures
  4. Additional labeling components (e.g., packaging)
  5. All of Module I

- What steps can we take to minimize the cost or other burdens of transitioning to an all-electronic submission environment?

  We believe that FDA should provide industry with a single comprehensive roadmap (including a proposed time table) for all electronic submission related initiatives (e.g., SPL, stability studies, RPS, etc.)

  We also request that FDA bring closer alignment/understanding between those involved in the drug review process and those involved with IT initiatives. We have found that

when we receive scientific requests for information from reviewers, it can be very difficult to determine how to organize our response in the current electronic submissions using the CTD structure. Often the information may fit in several sections and therefore may be difficult for those reading the submission to understand how we responded to the request. We ask that those designing the requirements for an all-electronic submission environment involve review staff in the process so that the modules can be organized in a way that allows for comprehensive responses to scientific requests. This could be accomplished by design of the submission structure, but also could be accomplished by permitting a certain amount of flexibility for those using that structure.

B. THIRD PARTY ENTITIES

- What are your general viewpoints on a third party entity or entities providing services related to such an electronic platform?

  We believe that use of a third party entity might be feasible, as long as:

  - The third party thoroughly understands the business of reviewing drugs and biologic products so that they can provide adequate support (e.g., providing guidance to the sponsor concerning the proper location for information not easily identifiable to the current CTD structure).
  - The third party is not the negotiating entity for how to handle submissions for new technologies (e.g., imaging). Those negotiations historically have required close cooperation between the sponsor and review division, and we believe it is very important for that practice to continue.
  - Use of a third party does not result in additional cost to the sponsors. We believe that there should be no extra burdens resulting from use of a third party, such as extra time needed to work with the third party, additional money required to build or use the system, and added complexities associated with the system.